REMARKS

The Final Office Action mailed December 17, 2008, has been carefully considered. The present Response is intended to be a complete response thereto and to place the case in condition for allowance.

Claims 32-73 are pending. Claims 32-55 and 68-73 have been withdrawn from consideration by the Examiner as being drawn to a non-elected invention. Claims 1-31 have been cancelled.

THE CLAIMS ARE NOT INDEFINITE

Claim 56 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse the rejection.

The Examiner alleges that the recitation of "Form I" is not an universal identification of the compound. Applicants respectfully submit that "Form I crystals of (+)-(S)-clopidogrel hydrogen sulphate" is defined in the specification and is generally accepted and has a clear meaning in the art. First, the specification on page 4, second paragraph, discloses that Form I is the same as that taught in WO 99/65915. Second, the prior art is replete with references to Form I clopidogrel hydrogen sulfate identifying the same crystalline form. For example, following U.S. patents extensively refer to Form I clopidogrel hydrogen sulfate (also known as clopidogrel bisulfate): 7,074,928; 6,767,913; 6,800,759; 7,291,735; 6,429,210; and 6,504,030. Therefore, contrary to the Examiner's allegation, Form I clopidogrel hydrogen sulfate is a well known an commonly accepted identification of a crystalline form of clopidogrel hydrogen sulfate, evidenced by its many references in the art.

In the Final Office Action, the Examiner alleges that Applicants' showing of references to Form I in prior U.S. patents "is not persuasive because an allowed application has no bearing on the merits of the instant application." Final Office Action, pages 2-3. Applicants respectfully submit that those patents (namely 7,074,928; 6,767,913; 6,800,759; 7,291,735; 6,429,210; and 6,504,030) are cited to show that Form I clopidogrel hydrogen sulfate is well-known, and has a consistent and definite meaning in the art. This evidence is relevant and clearly rebuts the Examiner's assertion that the use of "Form I" is indefinite.

> Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (A) The content of the particular application disclosure;
>
> (B) The teachings of the prior art; and
>
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

MPEP 2173.02 (emphasis added). In this case, the teachings of the prior art clearly shows that Form I has a definite meaning as it has been defined and referred to in U.S. Patent Nos. 7,074,928; 6,767,913; 6,800,759; 7,291,735; 6,429,210; and 6,504,030; and WO 99/65915. Additionally, the present disclosure clearly discloses that Form I is the same as that taught in WO 99/65915. The overwhelming evidence clearly leads to the conclusion that one skilled in the art would understand what is claimed by the phrase "Form I crystals of (+)-(S)-clopidogrel hydrogen sulphate."

Further, the Examiner alleges that "identical crystalline form can have drastically different powdered diffraction pattern while [*sic*] same X-ray diffraction pattern can be drawn to different chemicals." Final Office Action, page 3. As evidence, the Examiner refers to Bernstein, p. 118 and 272, but does not provide any explanation. It is not clear what the

Examiner is attempting to show in the XRPDs of Bernstein. However, page 118 of Bernstein shows an XRPD for sulphathiazole, an oral and topical antimicrobial, while page 272 shows an SRPD for Pigment Yellow 14. Not surprisingly, these are different compounds and thus have different XRPDs. Thus, comparison of page 118 and 272 of Bernstein does not support the Examiner statements that "identical crystalline form can have drastically different powdered diffraction pattern" or that the "same X-ray diffraction pattern can be drawn to different chemicals."

On page 118 of Bernstein, a calculated XRPD for sulphthiazole is compared to the actual XRPD. This does not support the Examiner's statement that "identical crystalline form can have drastically different powdered diffraction pattern" either. Page 118 of Bernstein only shows the discrepancy between a theoretically calculated XRPD and an actual XRPD. The two methods are drastically different which clearly explains the different patterns obtained; however, actual XRPDs should be consistently similar. None of the references cited by Applicants (to show that "Form I clopidrogrel hydrogen sulfate" is definite) uses theoretically calculated XRPD (all use actual XRPD).

Therefore, for the reasons noted, Applicants respectfully submit that claim 56 is not indefinite. Accordingly, Applicants request withdrawal of the rejection.

THE CLAIMS ARE ALLOWABLE

Applicants gratefully acknowledge the Examiner indicating claims 56-67 as being allowable if rewritten to overcome the rejection under 35 U.S.C. § 112, second paragraph. Applicants respectfully submits that because claim 56 is not indefinite (as discussed above), all claims are now in condition for allowance.

CONCLUSION

Applicants have responded to the Office Action mailed December 17, 2008. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Response or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (124907.0106). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicants hereby petition under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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